

*F 6*  
about 3 mm below said upper flat surface being smooth relative to said roughened threaded portion.

*gt K2*  
37. (Twice Amended) A titanium device to be surgically implanted in living bone, comprising a uniformly acid-etched exterior titanium metal surface from which a native oxide layer had been substantially removed and thereafter acid etched to produce a substantially uniform array of irregularities having base-to-peak heights of less than about 10 microns.

*P8*  
47. (Twice Amended) A titanium device to be surgically implanted in living bone and including a uniform exterior titanium metal surface from which a native oxide layer had been substantially removed and thereafter roughened to produce a substantially uniform array of irregularities having relatively uniform dimensions and peak-to-valley heights of less than about 10 microns, substantial numbers of said irregularities being substantially cone-shaped elements.

#### REMARKS

Claims 11-50 remain in the application for further prosecution. Independent claims 11, 17, 22, 27, 37, and 47 have been amended above in order to clarify the invention. Another set of the amended claims, marked up as required by 37 C.F.R. 1.121 (c)(ii), is enclosed. The specification has been amended in order to add a definition of the term "native oxide layer" as used herein. The definition is being transferred from the parent of the present application, which issued as US 5,876,453, and found at column 4, lines 1-30. Consequently, new matter should not have been introduced. A minor change was required in that Fig. 7 in the '453 patent is now Fig. 5 in the present application.

In the Advisory Action dated November 2, 2000, the Examiner noted that the Declaration of Keith Beatty lacked the date of execution. This was repeated in the present office action. On December 4, 2000 a new Declaration signed and dated by Keith

Beauty was submitted, which is assumed not to have reached the Examiner before the office action dated December 20 was mailed. The new declaration is believed to be satisfactory and therefore to have obviated the Examiner's request for a new declaration.

Claims 11-50 were rejected under 35 USC 112, under both the first and second paragraphs based on the use of the term "substantially" in connection with the removal of native oxide and the forming of a uniform roughness on a surface. In the above amendment, additional information has been added from a parent application in order to make clear what the Applicants considered to be native oxide and how one could determine when it had been removed. In part, a native oxide layer is defined with respect to the results of Auger electron spectroscopy, as illustrated in Fig. 5. Thus, one skilled in the art would be able to determine whether the native oxide layer had been removed or not. In general, the use of the term "substantially" is urged to be as accurate as the subject matter will permit. The use of Auger spectroscopy would enable one skilled in the art to determine from the Applicant's teachings that the metal surface was ready to be given a further treatment to provide the desired uniformly roughened surface.

The term "substantially" has also been used with respect to the description of the roughened surface for the same reasons. It should be evident from the photographs of titanium surfaces that the surface cannot be said to be perfectly uniform, since it is produced by the action of acids on the titanium and will be affected by several factors. One skilled in the art would understand that removing the native oxide would provide a titanium surface which would be attacked by acids in a more uniform manner. A more accurate description of the nature of the roughened surface does not appear feasible. Consequently, the Examiner is asked to reconsider and withdraw his rejections.

The Examiner has noted that he lacks copies of two references cited by the Applicants in the information disclosure statement. Copies of the Swiss patent and the Branemark article are enclosed for the Examiner's consideration.

Claims 11-16, 22-25, and 27-49 have been rejected under 35 USC 102(b) or 35 USC 103(a) based on the Krueger '434 patent. The teachings of Kruger are vague and the Applicants contend that one skilled in the art could not find even a suggestion of their invention. Consider first the metal used for the implant. The Applicants were concerned with titanium which has a surface oxide coating, referred to in the specification as the "native oxide". In contrast, Kruger says, at column 3, at line 40, "...a unitary member of a biocompatible or reasonably biocompatible material such as titanium or the like...". Even assuming that Kruger's implant was made of titanium, it is not clear that he considered the native oxide, merely referring to 'surface contaminants or impurities on the surface" at column 3, lines 54-55. Then, Kruger failed to provide information on how the etching was to be done. He says at column 3, lines 65 et seq, "The etching techniques which can be used in etching the surface 12 can correspond to those used in etching the electrodes of electrolytic capacitors. For this reason they are not set forth in detail in this specification. Normally, concentrated mineral acids are employed to etch such electrodes."

The Examiner seems to argue that the etched product of Kruger would have its native oxide layer removed and have irregularities of less than 10 microns. The Applicants contend that Kruger is insufficient to make even a *prima facie* case of obviousness and could not be fairly said to anticipate the Applicant's claims. The Applicant's invention is an implant from which native oxide has been substantially

removed and thereafter roughened to produce a uniform array of irregularities. Kruger does not even suggest such sequential treatments. Instead he indicates that etching with undefined "mineral acids" would be used. It is clear that Kruger's invention relates to the structure of the implant, not to the etching process. If one skilled in the art were to attempt to follow the teachings of Kruger it is more likely that the Applicant's surface would not result, since that person would have no information on how to proceed.

In his response to the Applicant's arguments, the Examiner has taken the position that any acid treatment such as those suggested by Krueger inherently would remove the native oxide layer. The Applicants have reported in Examples 1 and 2 that treatment with the same acid mixture used to roughen a titanium surface is not sufficient to remove all of the native oxide and that the surface is not uniformly roughened. If the Examiner is correct, it follows that the Applicant's two step process is unnecessary to achieve the desired results. The Examiner is asked to reconsider his comments; he reads too much into the vague disclosure of Krueger.

The Examiner also posits that the Applicant's are claiming a newly discovered feature of an old article. That conclusion could only be reached if it is assumed that any acid or combination of acids inherently removes the native oxide and allows the surface to be uniformly roughened. Again, the Applicants first remove the native oxide, as defined in the newly introduced material and thereafter uniformly roughen the surface with a second treatment. If that could be done in one step, the Applicant's process would be unnecessary. The commercial success of Applicant's Osseotite™ surfaced implants suggests otherwise.

The Examiner has also disagreed with the Applicant's suggestion that a smooth surface should be understood as being relative to another portion of the implant, the lower threads. Since "smooth" is a relative term, Claim 34 has been amended to clarify the meaning of the word.

The Applicants take issue with the Examiner's response to their previous comment that no information relating to etching of electrolytic capacitors could be found. The only information which would be relevant to the present application would pertain to etching of titanium, which was not found in what was felt to be a reasonable search. The three citations forwarded by the Examiner clearly are not pertinent to the issues in this case. Two relate to etching of aluminum and the third to etching of copper from electrodes. They merely teach that acids have been used to etch metals. The present application relates to etching of titanium surfaces to improve osseointegration of the titanium to living bone. The Applicants have found that a two step treatment provides superior performance in such uses. First remove the native oxide and then roughen the surface uniformly to provide peak to valley heights of less than 10 microns.

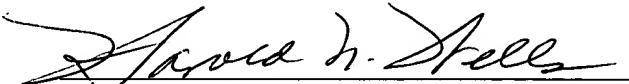
Claims 26 and 50 have been rejected under 35 USC 103(a) as unpatentable over Krueger in view of Wagner. As the Examiner has admitted, Krueger does not teach the use of both roughened and unroughened portions of an implant. In fact, he suggests that the entire implant should be roughened (see column 3, lines 50-53). Wagner suggests a different approach, that is to use porous material at the base of the implant, with a grit blasted portion above, leaving the top smooth. For most embodiments, Wagner does not use threads, but in Figure 4 an alternative is illustrated which appears to have threads

which are not roughened. Thus, combining Wagner with Krueger would not suggest the specific relation between the top and the threaded portions of the Applicant's implant.

In view of the amendments made above and the remarks relative to patentability of the invention over the cited art, the Applicants believe that the claims are in condition for allowance. If the Examiner believes that further amendment is needed, he is invited to contact the Applicants' attorney at the telephone number given below.

Respectfully submitted,

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